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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

NEKTAR THERAPEUTICS, Plaintiff/Counter-Defendant, v. ELI LILLY & CO., Defendant/Counter-Claimant.	CASE NO. 3:23-CV-03943-JD **ELI LILLY AND COMPANY'S COUNTERCLAIMS, ANSWER, AND AFFIRMATIVE DEFENSES** **DEMAND FOR JURY TRIAL** Judge: Hon. James Donato

COUNTERCLAIMS

Defendant and Counter-Claimant Eli Lilly and Company ("Lilly") brings these Counterclaims against Plaintiff Nektar Therapeutics ("Nektar") and alleges as follows:

INTRODUCTION

1. In early 2023, Nektar, a biopharmaceutical company, learned that rezpegaldesleukin ("REZPEG")—its primary asset and one of only three therapies in Nektar's pipeline—had recently failed a Phase 2 clinical trial. This was the second major failure for Nektar in as many years.

2. REZPEG's Phase 2 trial was the product of a 2017 co-development and license agreement between Nektar and Lilly. At the time, Lilly thought REZPEG showed promise for patients who had certain immunological conditions. Lilly agreed to pay Nektar $150 million to license the treatment, agreed to make future payments to Nektar if the treatment met certain milestones, and took on the bulk of REZPEG's development costs. In exchange, Nektar granted Lilly the right to jointly develop the treatment with Nektar. Over the next several years, Lilly invested tens of millions of dollars into clinical testing of multiple indications, hoping REZPEG would prove successful for patients. Unfortunately, it did not. Instead, trial results showed that REZPEG both failed its Phase 2 lupus trial (its lead indication) and caused injection site reactions or "ISRs"—red rashes that, in REZPEG's case, could grow the size of grapefruits—that undermined its potential as a treatment for skin conditions like atopic dermatitis.

3. After receiving the disappointing Phase 2 lupus results, Lilly informed Nektar on February 17, 2023 that it did not believe the parties should continue pursuing the lupus indication. Nektar was distressed by the news that its partner no longer believed REZPEG showed enough promise as a lupus treatment. As Nektar had disclosed in SEC filings, the company's success was "highly dependent on the success of [REZPEG]." In response, Nektar abandoned the collaborative tenor of the parties' relationship. It began publicly disparaging Lilly to shift attention away from REZPEG's shortcomings and to exert pressure on Lilly to relinquish REZPEG entirely to Nektar's control.

4. The very same day that Nektar publicly disclosed the unsuccessful Phase 2 lupus results, Nektar executives Howard Robin and Jonathan Zalevsky made public statements falsely blaming those results on very high bars that Lilly purportedly had unilaterally and unfairly set. In falsely attributing

REZPEG's failure to Lilly, Nektar intentionally created the misimpression that the lupus trial failed because Lilly exercised poor scientific judgment and imposed unreasonable standards on its collaboration partner—not that REZPEG had simply failed on the merits (as it had).

5. Nor was there an inkling of truth to Nektar's assertions that Lilly unilaterally caused REZPEG to flunk the Phase 2 trial. As Nektar knows, it and Lilly had discussed and ***jointly*** aligned on the clinical trial protocols and design parameters, including setting the specific endpoints that Nektar tried to pin on Lilly after the fact. Nektar's executives spread these falsehoods even after Lilly had pointed out that Nektar's statements were inaccurate and asked Nektar to correct them. Nektar knowingly and intentionally ignored Lilly's corrections, electing instead to publicly disparage Lilly in order to promote Nektar's false narrative.

6. Nektar also leveraged its false public statements to exert pressure on Lilly to terminate the Agreement. In March 2023, it demanded that Lilly terminate the License Agreement and return REZPEG to Nektar for development. Lilly ultimately made its own determination that REZPEG showed insufficient promise as an immunology therapy to warrant further investment. As a result, Lilly agreed in April 2023 to give up all its rights in the treatment, without receiving anything in return, despite having invested $150 million to license REZPEG, as well as tens of millions more in research and development expenses. Lilly's decision to return the asset to Nektar was a significant boon to Nektar because, if REZPEG proved successful, Nektar—as opposed to Lilly—would receive the payoff.

7. After the failed lupus trial and Lilly's termination, Nektar also needed to manufacture new interest in REZPEG. To this end, Nektar embarked on a coordinated public relations campaign in early August 2023, including an investor call and press release announcing revised data from two Phase 1 trials. The press release alleged Lilly had "incorrectly calculated" efficacy data from REZPG's Phase 1 atopic dermatitis and psoriasis trials. On the following day, during an investor call, Nektar executives doubled down on these false statements, stating multiple times that Lilly had "generated" the allegedly incorrect calculations. Worse yet, Nektar's statements implied that these calculation errors had impacted REZPEG's development and caused Lilly to terminate the License Agreement.

8. Nektar's statements were untrue, and its executives knew it. While a calculation error occurred in the Phase 1 clinical trials, Lilly did not make that mistake. Rather, a third-party contract

research organization ("CRO") that Nektar itself had recommended and that both parties had jointly agreed to hire made the error. Nektar was well aware of those facts—including that Lilly had correctly instructed the CRO on how to make the calculation—when it falsely and publicly blamed Lilly for the calculation error in August 2023.

9. Like the February 2023 statements about the lupus trial, Nektar's allegations created the misimpression that REZPEG's failures were Lilly's fault. According to Nektar, Lilly failed to carry out basic scientific tasks on two clinical trials. And it falsely accused Lilly of making a significant mistake in exercising its termination rights when REZPEG still showed significant promise—despite the fact that Nektar knew Lilly terminated the Agreement for other reasons and at Nektar's behest.

10. Nektar's public statements misattributing fault to Lilly violated the parties' License Agreement. In that contract, Nektar agreed it would not publish statements about REZPEG without Lilly's input and approval. But Nektar's executives repeatedly made their false statements about REZPEG and Lilly's work on it without first securing Lilly's approval; indeed, they did so over Lilly's express objections. Nektar's public statements falsely blaming Lilly for REZPEG's deficiencies were also defamatory.

11. Nektar's motive for falsely attempting to shift blame to Lilly is obvious: Nektar needed to deflect from REZPEG's shortcomings because the long-term viability of its business depends on REZPEG's success. But Nektar's desperation to bolster its fledgling treatment or to try to reassure the market that Lilly was to blame for the treatment's shortcomings does not justify breaching the parties' License Agreement or defaming Lilly.

PARTIES

12. Defendant and Counter-Claimant Lilly is a corporation organized under the laws of the State of Indiana with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is a pharmaceutical manufacturing company that discovers, develops, manufactures, and markets pharmaceutical products.

13. Plaintiff and Counter-Defendant Nektar is a corporation organized under the laws of Delaware with its principal place of business at 455 Mission Bay Boulevard South, San Francisco, California 94158.

JURISDICTION AND VENUE

14. The Federal District Court for the Northern District of California has subject matter jurisdiction pursuant to 28 U.S.C. § 1367(a), because these counterclaims are so related to the claims set forth in Nektar's Complaint that they form part of the same case or controversy. The Court has personal jurisdiction over Nektar because Nektar's principal place of business is in California and because Nektar has committed acts in this District that give rise to Lilly's claims.

15. Venue is proper in the Federal District Court for the Northern District of California pursuant to 28 U.S.C. § 1391 because Nektar has its principal place of business in this district and is subject to the Court's personal jurisdiction here. Venue is also proper because a substantial part of the events or omissions giving rise to Lilly's claims occurred in this district.

STATEMENT OF FACTS

A. Lilly Acquires the Right to Develop, Commercialize, and Sell REZPEG.

16. Lilly invests heavily in researching and developing new treatments for patients in its core therapeutic areas, including oncology, diabetes and obesity, neurodegeneration, pain, and immunology. Lilly contributes approximately 25% of its revenue to research and development.

17. Developing pharmaceutical treatments and medicines carries much risk and produces many failures. Only about 10% of medicines that complete a Phase 1 clinical trial are ever approved by the Federal Drug Administration, meaning the vast majority are never prescribed to patients. Recognizing these low probabilities, Lilly devotes resources to developing many treatments simultaneously, thus improving the likelihood that its pipeline will yield products that ultimately receive regulatory approval. This means that Lilly often develops competing products at the same time.

18. To maintain a robust pipeline, Lilly not only works to develop new treatments internally, but also acquires interests in technologies and therapies initially developed by other companies, including by smaller biotechnology companies like Nektar. When Lilly partners with a smaller company, Lilly often commits to incurring the majority of the development cost and assuming the associated financial risk if the treatment fails. In exchange, Lilly and its partners share in the upside, often through royalties that Lilly agrees to pay the company that licensed its technology.

19. Under this strategy, Lilly agreed in July 2017 to collaborate with Nektar to co-develop a novel immunological therapy called REZPEG pursuant to the terms of a license agreement (the "License Agreement").

20. At the time, REZPEG was in its infancy. The first dose had been administered to a human just two months before the parties announced their alliance. Despite the substantial uncertainties around REZPEG, Lilly was interested in the treatment's novel "mechanism of action," the biological process by which the treatment functions, which targets patients' interleukin-2 ("IL-2") receptor complex to stimulate their immune system. Lilly sought to explore this mechanism of action as a potential immunological treatment, which, if successful, could provide patients with an innovative option to treat immunological conditions. Given the promise Lilly saw in the treatment, Lilly agreed to pay Nektar $150 million in an initial lump sum payment for the rights to jointly co-develop REZPEG.

B. The License Agreement

21. Under the License Agreement, Lilly agreed to pay the vast majority of costs to develop, commercialize, market, and sell REZPEG, ranging from 75% to 100% depending on the phase of development and commercialization. License Agreement §§ 4.11, 5.3, 5.4. In exchange, Nektar granted Lilly an "exclusive . . . license . . . to develop, register, [and] sell" REZPEG worldwide and agreed Lilly would receive a majority of the proceeds of eventual sales if REZPEG proved successful. *Id.* § 2.1(a).

22. As part of the parties' bargain, Nektar got to keep the $150 million up-front payment whether or not REZPEG ultimately succeeded. *Id.* § 6.1. In addition, Lilly agreed to make four payments to Nektar of between $50 million and $75 million if REZPEG met certain milestones, plus certain royalties on future REZPEG sales. *Id.* §§ 6.2, 6.3.

23. Even though Lilly would overwhelmingly shoulder the burden to fund REZPEG's development, the parties agreed that Nektar would have a say in the treatment's development. Lilly agreed to provide Nektar equal input through a joint governance structure called the Joint Steering Committee, which was responsible for overseeing REZPEG's development. *Id.* §§ 3.1–3.2. Under this framework, the Joint Steering Committee designed and oversaw all aspects of REZPEG's testing and development. It was responsible for devising and overseeing a joint "Product Development Plan" and "Development Program" that covered all "the work performed by Nektar and Lilly . . . under this Agreement." *Id.* §§ 1.1,

3.2. The Joint Steering Committee was comprised of an equal number of representatives from Lilly and Nektar, and all the committee's decisions had to be unanimous. *Id.* §§ 3.1, 3.7(a). Below the Joint Steering Committee sat the Joint Product Team, which oversaw the operational implementation of REZPEG's testing and development. *Id.* § 3.4.

24. If Lilly and Nektar's representatives on the Joint Steering Committee could not agree on an issue, the License Agreement required the parties to escalate their disagreement through a contractually mandated dispute-resolution process that culminated in a meeting between the companies' respective executives. *Id.* § 3.7. If and only if the deadlock persisted for 14 days after the dispute was referred to the parties' executives, Lilly's position would ultimately prevail. *Id.* § 3.7(b)(i). Not once during the collaboration's entire history did either party have to use the Joint Steering Committee's dispute resolution process to resolve a disagreement between the parties.

25. Lilly was responsible for executing the trial design and development plan approved by the Joint Steering Committee and Joint Product Team. Given that REZPEG was in the earliest stages of development, however, Lilly made no promise that REZPEG would receive FDA approval, make it to market, or achieve any measure of success.

26. Instead, Lilly agreed to use "Commercially Reasonable Efforts" ("CRE")—as opposed to all efforts possible, no matter the cost—in carrying out "development activities." *Id.* §§ 4.1, 4.5, 4.9. Under the Agreement, Lilly was permitted to take into consideration the "market potential," "the competitiveness of the marketplace," and "commercial factors normally considered by [Lilly] in making product portfolio decisions" when expending effort and resources on REZPEG. *Id.* § 1.1.

27. Further, under the License Agreement, Nektar and Lilly recognized that Lilly would be developing products that may address the same conditions as, and even compete directly against, REZPEG. While Lilly agreed not to work on products that had the same mechanism of action as REZPEG, Nektar expressly "acknowledge[d] that . . . [Lilly] may now or in the future engage in research, manufacturing, development or commercialization activities that utilize technologies similar to or involve products competitive with" REZPEG. *Id.* §§ 12.1, 12.18.

28. The License Agreement also granted Lilly the unilateral, unqualified right to terminate the agreement at will for any reason. *Id.* § 11.2. If Lilly terminated, however, it would receive no refund

of the $150 million fee it had paid Nektar, nor the tens of millions of dollars it had expended in developing REZPEG. Rather, upon termination, Lilly would relinquish to Nektar all rights in REZPEG and relevant data from its development, after which Nektar would have full ownership of the treatment and all rights to any revenues the treatment might generate. *Id*. § 11.4.

29. Under the License Agreement, Lilly retained ultimate control over public statements. Specifically, Nektar had "no right to and shall not, publish or present any Product Specific Information or Technology that are necessary or useful for the development of the Product, without the prior written consent of Lilly." *Id*. § 12.6. Under the same provision, "[i]f Nektar request[ed] Lilly's consent for any publication," Nektar had to "afford Lilly a period of thirty (30) days to review any manuscript not yet presented for publication." *Id.* Further, Nektar was required to work together with Lilly to develop "a plan to promptly publish [clinical study data] at an appropriate scientific or medical meeting." *Id.* Pursuant to the License Agreement, these rights and obligations survived any expiration or termination of the Agreement. *Id.* § 11.6. In addition, any "external communications, including press releases and scientific disclosures," required approval from by both Nektar and Lilly through the Joint Steering Committee. *Id.* § 3.2(vii).

C. The Parties Make Lupus the "Lead" Indication and Begin Phase 1 Trials on Three Indications.

30. After executing the License Agreement in 2017, Nektar and Lilly decided on the indications that REZPEG would be developed to treat. Through the Joint Steering Committee process, Nektar and Lilly agreed to explore lupus, psoriasis, and atopic dermatitis (i.e., eczema) as potential indications for REZPEG.

31. On October 4, 2017, pursuant to the License Agreement, the parties jointly agreed that the treatment's "lead" indication would be lupus. This meant the parties would prioritize clinical trials and evaluation of lupus ahead of the other two indications, with the goal of leveraging the lupus results in evaluating the other two indications.

32. The road to regulatory approval and market for a treatment is long, generally involving three distinct phases of clinical trials. Phase 1 clinical trials are small scale studies (usually dozens of patients) that "include[] the initial introduction of an investigational new drug into humans." 21 CFR

§ 312.21(a). These studies are "designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness." *Id.*

33. Subsequent Phase 2 clinical trials involve a larger set of patients, typically several hundred. These studies are designed "to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug." 21 CFR § 312.21(b).

34. Finally, Phase 3 clinical trials—which involve thousands of patients and can cost hundreds of millions of dollars to conduct—are "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling." 21 CFR § 312.21(c). It is common for pharmaceutical manufacturers to start clinical trials and then discontinue them due to disappointing efficacy, unexpected side effects, and/or evaluations that the treatment will be difficult to market or commercialize.

35. At each stage in this process, pharmaceutical manufacturers set a clinical trial's endpoints and critical success factors ***before*** the trial begins. These predetermined criteria are typically safety and efficacy thresholds the manufacturer takes into consideration before proceeding with the next (and more costly) stage in the development process. Thus, when Lilly and Nektar worked to jointly design the Phase 1 trials for lupus, psoriasis, and atopic dermatitis, the parties agreed on specific endpoints for each of those trials.

36. It is common practice in the pharmaceutical industry to use a third-party contract research organization to perform certain clinical development activities, including conducting clinical trials. Lilly and Nektar agreed to use a CRO to conduct the Phase 1 studies for atopic dermatitis and psoriasis, including performing the calculations of study results. Nektar had a pre-existing relationship with a CRO—Pharmaceutical Research Associates, Inc. ("PRA")—which it had used for early testing of REZPEG. Eventually, on on February 24, 2021, ICON plc acquired PRA.

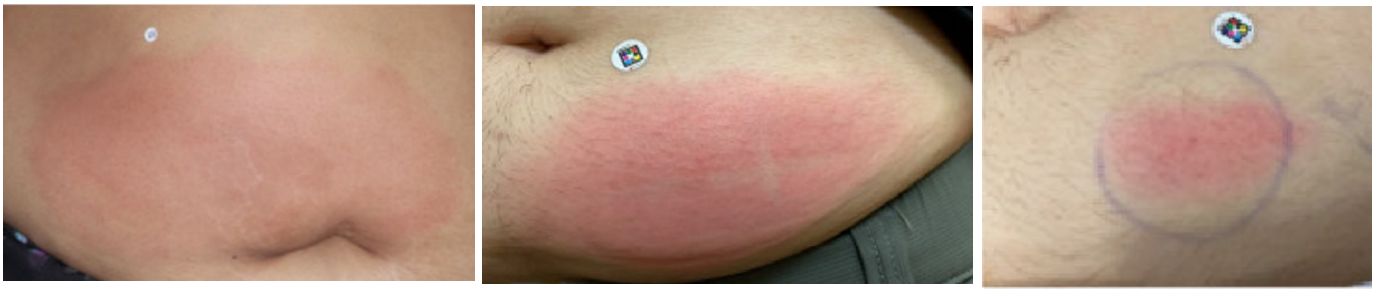
37. Nektar retained PRA for the Phase 1 lupus trial, which began in April 2018. On Nektar's recommendation, Lilly retained PRA as the CRO for the Phase 1 atopic dermatitis and psoriasis trials of

REZPEG. The parties began the Phase 1 study for atopic dermatitis in September 2019 and the Phase 1 study for psoriasis in November 2019. As with Phase 1 studies generally, Nektar and Lilly jointly designed the studies to evaluate REZPEG's safety compared to placebo before proceeding to Phase 2. *See* 21 CFR § 312.21(a).

D. Injection Site Reactions Severely Dampen REZPEG's Commercial Upside.

38. ISRs are an adverse reaction associated with treatments administered via injection, such as REZPEG. ISRs may include pain, swelling, rash, bleeding, redness, or other adverse reactions at the site of an injection.

39. During the Phase 1 clinical trials, it was apparent that REZPEG caused ISRs in a high proportion of patients tested. As shown below, patients treated with REZPEG developed red rashes that could be as large as tennis balls or even grapefruits at the injection site and that lasted two weeks on average after each REZPEG injection. Some subjects experienced pain and itching in the same area.



40. Eighty-five to 100% of healthy patients experienced ISRs. Among patients with atopic dermatitis and psoriasis, 75% and 71% of the patients tested, respectively, experienced ISRs. By comparison, among the subjects in the four Phase 3 clinical trials conducted for Dupixent®—an existing treatment for atopic dermatitis—only 8% to 14% experienced ISRs.[1] Moreover, the ISRs seen in REZPEG patients became more severe in the aggregate and lasted longer than ISRs seen with other injectable therapies.

41. ISRs can affect healthcare providers' choices when it comes to selecting treatments. All else equal, healthcare providers and patients choose treatments with fewer side effects. In the case of

[1] Frampton, et al., Dupilumab: A Review in Moderate-to-Severe Atopic Dermatitis, *Am. Journal of Clinical Dermatology*, (2018) 19:617-624.

REZPEG, this concern was particularly pronounced because Dupixent® was already approved and did not cause the same side effects as REZPEG.

42. Lilly apprised Nektar of the adverse ISR findings throughout the Phase 1 atopic dermatitis and psoriasis trials. On April 2, 2021, two Lilly researchers presented to the Joint Product Team on ISRs seen in patients to date, explaining that "ISRs contributed to discontinuations of multiple patients in the [Phase 1] psoriasis and atopic dermatitis studies." In other words, ISRs were causing multiple patients to drop out of clinical trials. The Lilly researchers concluded that REZPEG's attractiveness to patients "may be impacted by intensity and duration of ISRs, especially in dermatological diseases," like psoriasis and atopic dermatitis, and that the REZPEG team should seek "to avoid a situation where a high efficacy treatment has limited developability due to ISRs, or make a commercial decision without understanding the path to mitigate ISRs." Ten Nektar employees attended the meeting, including its Chief Research and Development Officer, Jonathan Zalevsky, and its Chief Medical Officer and Head of Clinical Development, Brian Kotzin.

43. During the same April 2, 2021 meeting, the Joint Product Team unanimously endorsed the design and cost of a separate, independent clinical study to specifically analyze the cause of ISRs in patients receiving REZPEG and to identify potential mitigation strategies. That same day, the Joint Steering Committee unanimously approved the independent ISR-focused study at a cost of up to $5 million, to be borne by Lilly. This supplemental study was designed to evaluate what options were available after the disappointing ISR data from the initial trials. In other words, Lilly spent another $5 million on top of the tens of millions already spent to see if there was a solution to the ISR issues the parties had identified.

44. Unfortunately, the additional results were disappointing. On November 19, 2021, four Lilly team members presented the preliminary results of the supplemental ISR study to the Joint Product Team, including to Zalevsky, Kotzin, and nine other Nektar employees. Those results showed that ***100% of subjects*** in the study experienced ISRs in the form of red rashes at the injection site. Most also experienced itching and pain. Among subjects who received REZPEG injections in the thigh, 80% experienced itching from ISRs, while 70% experienced ISR-related pain. Among those who received a high dose of REZPEG spread out across two abdomen injections, 50% experienced pain, 90% experienced

some itching, and 50% experienced severe itching. ISRs in some subjects lasted for up to two to four weeks after the patients discontinued using REZPEG.

45. In addition to the ISR clinical study, Lilly commissioned and funded market research by The Link Group and Harper Global to determine how a high rate of ISRs might impact prescribers' and patients' willingness to choose REZPEG over other therapies treating the same condition. Lilly informed Nektar about its decision to conduct this market research at the September 8, 2021 meetings of the Joint Product Team and Joint Steering Committee, and Nektar voiced no objection.

46. In the fall of 2021, The Link Group conducted ISR market research of health care providers and patients to compare their relative preferences for a new treatment with REZPEG's potential characteristics against those of two existing treatments for atopic dermatitis (Dupixent® and a JAK inhibitor) and one available treatment for lupus (Benlysta®). At that time, Dupixent® was the dominant treatment for atopic dermatitis.

47. The Link Group measured provider and patient preferences across various assumed characteristics of REZPEG, including different levels of efficacy and different levels of ISR severity. In October 2021, The Link Group concluded that health care providers and patients' interest in an atopic dermatitis or lupus therapy declined proportionately with the frequency and severity of ISRs. Indeed, health care providers and patients were willing to accept products with lower efficacy if that meant less severe ISRs.

48. The impact of ISRs was especially problematic among health care providers treating patients with atopic dermatitis. Those respondents rated their preference for REZPEG, Dupixent®, and a JAK inhibitor, assuming three different efficacy levels for REZPEG (low, moderate, and high) and four different levels of severity of ISRs. Preference for REZPEG declined as the severity of ISRs increased. If respondents assumed REZPEG caused severe ISRs, a higher share of providers preferred Dupixent®, even if REZPEG otherwise performed significantly better than that alternative.

49. The Link Group's research showed that converting users of Dupixent® to REZPEG for treatment of skin diseases would be difficult, given that Dupixent® had relatively low ISR rates. Moreover, REZPEG was unproven, and had in no way shown itself to be more effective, much less significantly more effective, than Dupixent®.

50. In light of these concerns with the prevalence of ISRs among REZPEG users, Lilly and Nektar continued to jointly discuss and analyze potential mitigation strategies. They also aligned on commissioning additional ISR-focused market research from The Link Group, as well as a second market research consulting company, Harper Global. Indeed, Lilly was committed to exploring all possible mitigations for ISRs experienced by REZPEG patients, as it had already devoted substantial resources to the treatment, spending tens of millions of dollars on its development in 2021 alone.

51. At the same time, the parties worked together to jointly complete the Phase 1 trials. The parties completed the Phase 1 trials for lupus on August 29, 2019, psoriasis on July 21, 2021, and atopic dermatitis on June 24, 2022. At the conclusion of those Phase 1 trials, REZPEG met its pre-determined endpoints for both lupus and atopic dermatitis. The parties jointly agreed to proceed with Phase 2 trials for lupus and atopic dermatitis, while also continuing to work towards the goal of mitigating ISRs.

E. REZPEG's Lupus Phase 2 Clinical Trial Misses Endpoints.

52. The REZPEG Phase 2 lupus trial began in August 2020. Before commencing that study, Nektar and Lilly jointly agreed on the study protocol, design, and required endpoints. On July 31, 2019, the parties agreed on the primary endpoint REZPEG needed to meet in the Phase 2 lupus trial: a 4-point reduction in the SLEDAI-2K score, a widely used metric to measure and stratify the severity of lupus. The trial completed in February 2023.

53. The results of the lupus study showed REZPEG had failed to meet the study's primary endpoint. The proportion of trial subjects that reached a 4-point reduction in the SLEDAI-2K score while on high and low doses of REZPEG was nearly identical to the proportion that reached the same reduction while on a placebo. Thus, REZPEG did not demonstrate any measurable differentiation in SLEDAI-2K score. While subjects on a middle dose of REZPEG fared marginally better, the difference compared to placebo recipients was not statistically significant, again representing a failure to meet the predetermined 4-point threshold.

54. Because REZPEG's efficacy results did not show a measurable difference from a placebo and given the continued high incidence of ISRs—seen in over 80% of subjects in the highest dosing group in the Phase 2 trial—Lilly determined on February 16, 2023 that the "risk-benefit profile" did not justify advancing the treatment to Phase 3 for lupus. Accordingly, Lilly decided to proceed no further with lupus

clinical testing and to drop lupus as an indication for REZPEG. Lilly informed Nektar of its decision the next day, during the February 17, 2023 Joint Steering Committee Meeting.

55. On February 20, 2023, the Joint Steering Committee held an ad hoc meeting to discuss the results and Lilly's decision not to pursue lupus as an indication for REZPEG. During the meeting, Nektar and Lilly both agreed that they needed to further discuss the planned Phase 2 atopic dermatitis trial, including whether to move forward with it in light of the discouraging lupus results.

F. Nektar Panics Amid Fallout from REZPEG's Phase 2 Failure.

56. REZPEG's Phase 2 clinical trial failure and the subsequent decision to drop lupus as an indication were terrible news for Nektar. This was the second major failure for a Nektar treatment in clinical trials in as many years. In 2022, Nektar's cancer immunotherapy treatment NKTR-214 (also known as bempegaldesleukin)—which Nektar had licensed to Bristol Myers Squibb—failed to meet its endpoints in Phase 3 trials.

57. Nektar knew the success of its business depended on salvaging REZPEG, one of just three treatments remaining in its pipeline. In a filing with the SEC on November 4, 2022, before Nektar released the Phase 2 lupus results, Nektar stated that the company was "highly dependent on the success of [REZPEG]" and its "business will be significantly harmed if [REZPEG] do[es] not continue to advance in clinical studies." In the same filing, Nektar referred to REZPEG as its "lead drug candidate."

58. Following REZPEG's disappointing Phase 2 lupus results in February 2023, Nektar shifted into self-preservation mode and abandoned the collaborative tenor that had characterized the parties' relationship between 2016 and 2022. Nektar instead set out on a communication strategy to launder the reputation of what had been its star treatment and to attempt to blame REZPEG's shortcomings entirely on Lilly.

59. The first step in Nektar's plan to bolster REZPEG was to whitewash the lupus Phase 2 clinical trial results. Nektar had scheduled an investor call for February 23, 2023, and was determined to use the call to publicly disseminate a false narrative that Lilly, not REZPEG, was the supposed cause of the adverse Phase 2 results.

60. On February 21 and 22, 2023, Nektar sent Lilly a proposed draft press release, slide deck, and Q&A script for the upcoming investor call. The three drafts contained multiple falsehoods, including

that Lilly had supposedly made the decision not to advance REZPEG to Phase 3 lupus trials based on endpoints that Lilly had unilaterally and unreasonably imposed. In reality, Lilly and Nektar had jointly aligned on the endpoints used in the lupus Phase 2 trial, which REZPEG had failed to satisfy.

61. On February 23, 2023, Lilly provided comments and edits to all three documents, including revising "several suggestions [made by Nektar] that Lilly unilaterally made decisions about the development program." As Lilly explained to Nektar at the time, "development decisions were discussed and aligned on at the appropriate governance committee meetings and such matters were never escalated to senior leadership nor did Lilly exercise any post-escalation final decision making in this regard." Lilly stated expressly to Nektar that "Lilly's approval of each document is contingent on Nektar's incorporation of all of Lilly's comments and edits."

62. Lilly's corrections to Nektar's draft documents were accurate and necessary. Nektar had participated in and agreed to all the clinical trial protocols and design parameters. Not once did Nektar invoke the contract's dispute resolution process. Rather, Nektar and Lilly's representatives discussed and aligned on each decision on clinical trial protocols and design parameters ***unanimously***.

63. Nonetheless, Nektar charged ahead with its public statements. On February 23, 2023, Nektar issued its press release and presented the slide deck at an investor call without incorporating Lilly's revisions. In those public statements, Nektar expressly blamed Lilly—rather than REZPEG—for the failed lupus Phase 2 trial. Nektar executives—including Zalevsky, Kotzin, and Nektar CEO Howard Robin—likewise made statements during the investor call that did not reflect Lilly's edits to the Q&A script; instead, the Nektar executives falsely asserted that the decision not to proceed with Phase 3 lupus trials was based on "[Lilly's] need for the [Phase 2] study to have reached very high bars," and that Lilly chose the endpoints for the Phase 2 study.

64. The misleading nature of these statements is evidenced by Nektar's recent decision to forego lupus as an indication for REZPEG, even as it develops the treatment on its own. In other words, it was not just Lilly that dropped lupus as an indication during the parties' collaboration arrangement. Rather, even after the partnership ended, and Nektar had complete control over the treatment's development, Nektar chose not to move REZPEG into Phase 3 trials for lupus. That is because REZPEG is not a viable treatment for lupus, as Lilly concluded at the time.

65. Nektar made its misstatements to investors and potential customers in breach of its contractual obligation to obtain consent and approval from Lilly before releasing public statements regarding REZPEG. Indeed, Lilly had explicitly objected to all of them. The statements likewise painted Lilly as an uncooperative and unproductive development partner, tarnishing its reputation in the market and among current and potential partners.

66. Nektar made these false statements here, even though it has been previously accused of misleading the market to protect other fledgling treatments. In 2021, Nektar shareholders accused Nektar officers and directors, including Robin and Zalevsky, of making misleading and false public statements about clinical trial results for NKTR-214. *See Zavialova v. Robin, et al.*, Case No. 2021-0118, 2021 WL 653018 (Del. Ch. 2021). Specifically, Nektar was accused of making repeated false claims that the treatment had shown a "30-fold increase" in production of cancer-fighting cells in early trials, an assertion "based on cherry-picked data" derived from an outlier patient. *Id.* ¶¶ 4, 5. The suit relied, in part, on an October 2018 report published by Plainview LLC, a biotechnology research company, entitled "Pegging the Value of NKTR-214 at Zero."[2] The report asserted that Nektar had misleadingly reported results for only 31% of participants in recent clinical trials for NKTR-214, skewing the results to appear more favorable. Contrary to Nektar's public assertions at the time regarding that treatment, the report stated that the treatment itself was "too weak to work" and was "missing the bar for efficacy by a wide margin."[3]

67. The suit further accused Nektar executives of overstating the company's collaboration with Bristol Myers Squibb to develop the treatment. *Zavialova*, 2021 WL 653018, ¶¶ 115-130. Indeed, according to the suit, Nektar executives repeatedly stated that the the collaboration planned to run clinical trials in more than 20 indications, when, in reality, they were only testing in five or six. *Id.* Worse yet, the Nektar shareholder accused Nektar executives of selling their Nektar stock prior to disclosures revealing the truth regarding NKTR-214 and Nektar's collaboration with Bristol Myers Squibb—to the tune of $171 million in stock sales. *Id.* ¶ 1. Nektar appears not to have learned any lessons from the fallout over its public statements regarding NKTR-214.

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[2] https://seekingalpha.com/article/4209320-pegging-value-of-nktrminus-214-zero

[3] *Id.*

G. Nektar Pushes Lilly to Terminate the Agreement and Continues Its PR Campaign.

68. Realizing that it could not simultaneously point the finger at Lilly and move forward in its partnership with Lilly, Nektar began pushing Lilly to terminate the License Agreement. Critically, only Lilly—not Nektar—had the right to terminate at will under the contract. On March 23, 2023, Nektar's Robin demanded that Lilly executives agree to terminate the parties' License Agreement and return all rights to REZPEG, a demand that he reiterated in an April 1, 2023 email.

69. After assessing REZPEG's treatment potential, including the persistent ISRs and the disappointing Phase 2 lupus results, Lilly determined the treatment showed inadequate promise for patients to warrant further investment. On April 4, 2023, Lilly told Robin that it would agree to negotiate the termination of the License Agreement and the process of transferring to Nektar Lilly's rights to REZPEG and relevant data. Lilly required no consideration from Nektar in return.

70. The termination, however, would leave Nektar without a development partner or a much-needed funding source. By April 2023, Nektar was experiencing such extreme financial hardship that it reduced its San Francisco-based workforce by approximately 60%. In order to bolster its fledgling treatment and reinvigorate its business, Nektar doubled down on its public claims that REZPEG was a promising treatment that was just being dragged down by its development partner—Lilly.

71. On April 16, 2023, Nektar sent another draft press release to Lilly, noting that it intended to issue the statement the following day, violating its contractual requirement to afford Lilly at least 30 days to review any publication for which Nektar was seeking Lilly's consent to publish. License Agreement § 12.6. This draft contained multiple misstatements and falsehoods, including that the decision to return REZPEG to Nektar was a result of "Eli Lilly's other priorities in atopic dermatitis." This was a thinly veiled reference to another atopic dermatitis treatment that Lilly was developing, lebrikizumab ("Lebri"). Lebri was initially developed by another biopharmaceutical company, Dermira, Inc., which Lilly had acquired in January 2020.

72. Nektar's statement was false, as Lilly had devoted significant resources to both REZPEG and Lebri. Indeed, Lilly was strongly incentivized to make ***both*** REZPEG and Lebri a success for patients. REZPEG's success did not preclude Lebri's success, or vice versa.

73. Moreover, Nektar's statement implying wrongdoing by Lilly ignored Lilly's rights under the License Agreement to develop potentially competitive products so long as they had a different mechanism of action than REZPEG, which Lebri indisputably did. License Agreement §§ 1.1, 12.1(a), 12.18.

74. Finally, Nektar knew Lilly had already expended significant time and money developing REZPEG. Lilly had worked with Nektar to design and execute over a dozen clinical studies, including completing multiple Phase 1 trials, the Phase 2 lupus trial, as well as additional studies focused on targeted clinical issues, such as ISRs. It was therefore not Lilly's lack of effort that caused Lilly to drop lupus as an indication, but instead REZPEG's failures in clinical testing. And it was Nektar, not Lilly, that pushed to terminate the License Agreement.

75. Upon seeing the April 16 draft press release, Lilly promptly objected to it, noting that the release mischaracterized Lilly's "prioritization" of REZPEG. Lilly further informed Nektar that the draft contained statements that violated the License Agreement and were false and defamatory.

76. In response, Nektar drafted an entirely new press release that it sent to Lilly at 4:36 p.m. ET on April 17. Nektar issued its newly drafted press release less than an hour later, giving Lilly no time to review and respond to it. Nektar's April 17, 2023 press release portrayed REZPEG to investors in rosy terms, proclaiming that the treatment had generated "strong data" in clinical trials, and that "the stage was set" to "move quickly" into a Phase 2 trial for atopic dermatitis. It also impermissibly alluded to the parties' confidential termination negotiations. By releasing the April 17 press release without Lilly's consent or approval, Nektar again breached the License Agreement.

77. Lilly explained as much to Nektar on April 19, 2023, when it told Nektar that it had "not afforded [Lilly] an opportunity to review or approve [the April 17, 2023 press release] as required by our License Agreement," that Lilly did "not approve of the language in the press release that was publicly released," and that Nektar's actions were "in direct violation of our License Agreement."

H. Nektar's Campaign Escalates to Falsely Accusing Lilly of Clinical Trial Errors.

78. Nektar's attempts to blame Lilly for REZPEG's failure culminated with coordinated public accusations against Lilly in early August 2023. These accusations were designed to create new interest in REZPEG's potential as an atopic dermatitis treatment given Nektar had independently

determined Lilly was right about the lupus data. At the same time, Nektar sought again to blame Lilly for REZPEG's troubles to date.

79. First, Nektar issued yet another press release without Lilly's consent or approval and, in fact, failed to seek it altogether. In that press release, Nektar released new efficacy data for REZPEG's Phase 1 psoriasis and atopic dermatitis trials based on a calculation error that Nektar discovered after Lilly had terminated the Agreement. The erroneous calculations for the clinical trials were performed by the CRO for those trials, ***not Lilly***. Nektar had specifically recommended and approved engaging the CRO to administer the studies and to perform the challenged calculations. Nektar flagged the issue earlier in 2023, and Lilly worked with Nektar in answering questions about the data.

80. Nevertheless, Nektar repeatedly publicly stated—without warning—that Lilly had incorrectly calculated results from the atopic dermatitis and psoriasis Phase 1 trials:

- "[E]fficacy data previously generated by Eli Lilly & Company for rezpegaldesleukin (REZPEG) . . . were incorrectly calculated ***by Lilly***."
- "The erroneous data is from two Phase Ib studies for REZPEG that were conducted ***by Lilly***."
- "Nektar discovered the EASI-related and Psoriasis Area and Severity Index (PASI)-related clinical efficacy endpoints were incorrectly calculated ***by Lilly*** after all rights to REZPEG were returned to Nektar."

81. Nektar then repeated and elaborated on these false statements in an investor call the following day. Nektar executives Robin and Zalevsky both stated multiple times that Lilly had "generated" the allegedly incorrect calculations.

82. Nektar was fully aware that these statements were false, given the CRO made the mistake. And the protocols for the Phase 1 atopic dermatitis trial and the Phase 1 psoriasis trial included the correct calculations. Both of these protocols were reviewed and approved by Nektar before either clinical trial began.

83. Nektar's suggestion that "Lilly's" supposed calculation error concerning the Phase 1 efficacy results caused Lilly to discontinue the clinical trials of REZPEG was likewise untrue. The CRO's Phase 1 calculation errors made no material difference to REZPEG's development. Notwithstanding the

CRO's miscalculations, Nektar and Lilly agreed to move ahead with the Phase 2 lupus study and with designing the Phase 2 atopic dermatitis study. Lilly's eventual decision to terminate the agreement—at Nektar's insistence—was not the result of the Phase 1 atopic dermatitis or psoriasis trials, but rather the prevalence and severity of ISRs seen in REZPEG patients and the disappointing Phase 2 lupus results.

84. Nektar made these false and defamatory statements regarding Lilly with the obvious hope of convincing investors and potential customers that the dissolution of Nektar's partnership with Lilly had nothing to do with REZPEG's market potential and everything to do with Lilly's purported incompetence. Nektar believed the treatment could only be rehabilitated by publicly suggesting Lilly had botched the Phase 1 atopic dermatitis and psoriasis trial results, which led it to prematurely terminate the partnership and REZPEG's development.

85. To this end, Nektar falsely proclaimed Lilly to be inept and ineffective at performing clinical trials—a bedrock of its pharmaceutical-development business, thereby damaging Lilly's reputation among investors, potential and current partners, doctors, and patients.

FIRST COUNTERCLAIM

(Breach of License Agreement)

86. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

87. Nektar is a party to the License Agreement with Lilly.

88. Lilly performed all of its obligations under the License Agreement.

89. The License Agreement prohibits Nektar from publishing or presenting any confidential information regarding REZPEG controlled by Nektar "without the prior written consent of Lilly." License Agreement § 12.6. Under the License Agreement, Nektar must provide Lilly "a period of thirty (30) days to review any manuscript not yet presented for publication," and Lilly may reasonably delay any publication "as Lilly in good faith believes necessary to protect Lilly's rights." *Id.* These requirements survived termination of the Agreement in April 2023. *Id.* § 11.6.

90. The License Agreement further provides that the Joint Steering Committee must "approv[e] external communications, including press releases and scientific disclosures." *Id.* at § 3.2(vii).

91. Nektar breached Sections 3.2(vii) and 12.6 of the License Agreement when it issued the following documents and statements publicly, without Lilly's prior written consent, without affording

Lilly a reasonable opportunity to review and comment on the documents before publishing them, and without obtaining approval from the Joint Steering Committee:

i. Nektar's February 23, 2023 press release;

ii. Nektar's slide deck presented during the February 23, 2023 investor call; and

iii. Statements made by Nektar's Howard Robin and Jonathan Zalevsky during the February 23, 2023 investor call.

92. Nektar breached Section 12.6 of the License Agreement when it issued the following documents and statements publicly without Lilly's prior written consent and without affording Lilly a reasonable opportunity to review and comment on the documents before publishing them:

i. Nektar's April 17, 2023 press release;

ii. Nektar August 7, 2023 press release; and

iii. Statements made by Howard Robin and Jonathan Zalevsky during the August 8, 2023 investor call.

93. As a direct and proximate result of Nektar's breaches, Lilly has suffered damages in an amount to be proven at trial.

SECOND COUNTERCLAIM

(Defamation)

94. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

95. In multiple documents and oral communications that Nektar prepared and publicly released on February 23, 2023, Nektar made unprivileged and false statements about Lilly to the public at large that Nektar knew were false, were defamatory per se, and caused Lilly reputational harm. For example, Nektar stated publicly that REZPEG's failure to meet the pre-determined endpoints in the Phase 2 lupus clinical trial was a result of criteria Lilly had unilaterally imposed that set unreasonably high bars for REZPEG to meet. Nektar knew this statement was false at the time Nektar made it.

96. Nektar made such defamatory statements in the following documents published and publicly available:

i. Nektar's February 23, 2023 press release;

ii. Nektar's slide deck presented during the February 23, 2023 investor call; and

iii. Statements made by Howard Robin and Jonathan Zalevsky during the February 23, 2023 investor call.

97. In multiple documents publicly released in August 2023, Nektar continued to make public, unprivileged, and false statements about Lilly to the public at large that Nektar knew were false, were defamatory per se, and caused Lilly reputational harm. For example, Nektar stated publicly that Lilly—a major pharmaceutical company that performs clinical trials regularly—"incorrectly calculated" clinical trial data.

98. Nektar made these statements in the following documents published and publicly available:

i. Nektar's August 7, 2023 press release; and

ii. Statements made by Howard Robin and Jonathan Zalevsky during the August 8, 2023 investor call.

99. Nektar knew these statements were false when Nektar made them. Nektar and Lilly had jointly agreed to and endorsed the study protocol and design the the Phase 2 lupus trials, including the endpoints. Moreover, Nektar was fully aware that the calculation errors were made by the parties' agreed-to CRO, not by Lilly, and that Nektar and Lilly had agreed on the protocol for the CRO to follow.

100. Falsely accusing Lilly of making mistakes in clinical trial design and execution has a natural tendency to harm Lilly's business reputation. Lilly depends on the trust of doctors, patients, regulators, and investors in its ability to safely bring effective pharmaceutical treatments to the market. Nektar's defamatory statements strike at the heart of Lilly's business reputation as a trusted source of pharmaceutical treatments.

101. Lilly also relies on the trust of potential partners in co-development agreements to bring promising new treatments to market. Nektar's defamatory statements have a natural tendency to discourage other pharmaceutical companies from partnering with Lilly to develop and commercialize new pharmaceutical treatments and therapies.

102. When it made the false statements that Lilly had improperly designed clinical trials and had made calculation errors, Nektar knew the statements would injure Lilly's reputation as a leader in clinical trials and pharmaceutical development.

103. As a direct and proximate result of Nektar's breaches, Lilly has suffered damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Defendant and Counter-Claimant Lilly respectfully requests judgment as follows:

1. That judgment be entered in favor of Lilly and against Nektar;

2. For compensatory damages in an amount to be proved at trial;

3. That Lilly be awarded pre- and post-judgment interest;

4. That Lilly be awarded its costs and expenses in connection with this action, including attorneys' fees and expenses; and

5. That the Court award Lilly such other and further relief as may be just and proper.

JURY DEMAND

Pursuant to Federal Rules of Civil Procedure 38(b), Lilly hereby demands trial by jury of all issues properly triable thereby.

* * *

ANSWER AND AFFIRMATIVE DEFENSES

Defendant and Counter-Claimant Eli Lilly and Company ("Lilly"), by and through its undersigned counsel, hereby submits its Answer and Defenses to Plaintiff Nektar Therapeutic's Complaint (ECF No. 1 resubmitted per order at ECF No. 25, "Complaint").

Lilly denies any and all allegations of wrongdoing and denies that Plaintiff is entitled to any relief. To the extent that the Complaint's headings or subheadings contain factual allegations, they are denied. Lilly further answers as follows:

INTRODUCTION

1. Lilly admits that it is one of the world's leading pharmaceutical companies. Lilly also admits that it entered a joint development agreement with Nektar regarding Nektar's biologic drug therapy candidate rezpegaldesleukin ("REZPEG"). Lilly denies the remaining allegations in Paragraph 1.

2. Lilly admits that a third-party contract research organization ("CRO"), which Nektar itself had recommended and which both parties had jointly agreed to hire, made a calculation error in certain Phase 1 clinical trials. Lilly denies the remaining allegations in Paragraph 2.

3. Lilly admits that data from the Phase 1 clinical trials containing the CRO's calculation error were published. Lilly admits that Nektar's revised calculations of the clinical trial data show 83% efficacy in treating atopic dermatitis after 12 weeks of therapy. Lilly denies the remaining allegations in Paragraph 3.

4. Lilly denies the allegations in Paragraph 4.

THE PARTIES

5. Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the allegations in Paragraph 5, and denies those allegations on that basis.

6. Lilly admits the allegations in Paragraph 6.

JURISDICTION AND VENUE

7. Paragraph 7 characterizes Nektar's claims or states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly admits that the Federal District Court for the Northern District of California has subject matter and personal jurisdiction over Lilly. Lilly denies any allegation that it engaged in improper conduct or that the claims asserted against it have merit.

8. Paragraph 8 characterizes Nektar's claims or states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly admits that venue is proper in the Federal District Court for the Northern District of California. Lilly denies any allegation that it engaged in improper conduct or that the claims asserted against it have merit.

FACTUAL BACKGROUND

Autoimmune Disorder Therapeutics

9. Lilly admits the allegations in Paragraph 9.

10. Lilly admits that currently available therapeutics for the treatment of autoimmune diseases can be broadly acting, non-disease specific, and can cause side effects. Lilly admits that some patients do not respond optimally to these treatments or do not respond at all. Lilly admits that there is a need for new autoimmune disorder therapeutics. Lilly admits that the market for autoimmune disorder treatments has increased. Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the remaining allegations in Paragraph 10, and denies those allegations on that basis.

11. Lilly admits that certain biologics can be effective at treating some autoimmune disorders. Lilly also admits that the antibody belimumab (Benlysta®) is an FDA-approved biologic for systemic lupus erythematosus. Lilly admits that Humira®, Enbrel®, and Stelara® have been approved to treat moderate-to-severe chronic plaque psoriasis. Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the remaining allegations in Paragraph 11, and denies those allegations on that basis.

12. Lilly admits the allegations in Paragraph 12.

13. Lilly admits that mild cases of atopic dermatitis can sometimes be treated with lifestyle changes and topical drugs and ointments such as corticosteroids. Lilly also admits that, when these treatments are ineffective, additional therapies may be used. Lilly admits that Dupixent® (known generically as dupilumab) is a leading treatment for moderate-to-severe atopic dermatitis. Lilly also admits that Dupixent® is a biologic drug (antibody) that is injected under the skin and is believed to suppress immune activity and inflammation by blocking signals in the body associated with the molecules interleukin-4 ("IL-4") and interleukin-13 ("IL-13"). Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the remaining allegations in Paragraph 13, and denies those allegations on that basis.

14. Lilly admits that Nektar's REZPEG (also known as NKTR-358 and later LY3471851) is a candidate therapy for autoimmune disorders, including moderate-to-severe atopic dermatitis. Lilly admits that REZPEG is a biologic (a derivative of the molecule interleukin-2) that is injected under the skin. Lilly admits that it hoped that REZPEG could regulate immune activity and inflammation and restore balance in the immune system by prolonging the natural immunoregulatory activity of interleukin-2 ("IL-2"). Lilly admits that Nektar reported in an early study of REZPEG that REZPEG "delivers sustained, preferential activation of" regulatory T cells. Lilly admits that regulatory T cells suppress immune system activity and regulate the body's immune response. Lilly admits that Nektar reported in another early study of REZPEG that "[a] single dose of [REZPEG] in cynomolgus monkeys resulted in sustained activity that lasted for at least 14 days compared with the transient response in rhIL-2 treated animals." Lilly denies the remaining allegations in Paragraph 14.

15. Lilly admits that REZPEG's IL-2 mechanism of action is different than the mechanism of action for Dupixent®. Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the remaining allegations in Paragraph 15, and denies those allegations on that basis.

Nektar-Lilly Partnership Under the 2017 Agreement and Early REZPEG Development

16. Lilly admits that Nektar selected Lilly to be its joint development partner for REZPG development. Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the remaining allegations in Paragraph 16, and denies those allegations on that basis.

17. Lilly admits that, on or about July 23, 2017, Nektar and Lilly entered into a license agreement ("Agreement") to collaborate on the development of REZPEG. Lilly also admits that it hoped that REZPEG had significant therapeutic potential to be a successful autoimmune therapeutic. Lilly admits that Paragraph 17 accurately quotes from its press release dated July 24, 2017 about its alliance with Nektar. Lilly admits that the parties contemplated developing REZPEG for use in indications such as moderate-to-severe systemic lupus erythematosus, moderate-to-severe-atopic dermatitis, and moderate-to-severe chronic plaque psoriasis. Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the remaining allegations in Paragraph 17, and denies those allegations on that basis.

18. Paragraph 18 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies the remaining allegations in Paragraph 18.

19. Paragraph 19 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies the remaining allegations in Paragraph 19.

20. Paragraph 20 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies the remaining allegations in Paragraph 20.

21. Paragraph 21 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies the remaining allegations in Paragraph 21.

22. Paragraph 22 characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies the remaining allegations in Paragraph 22.

23. Paragraph 23 characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly admits that a subcontractor was engaged to conduct statistical analysis of the Phase 1 atopic dermatitis and plaque psoriasis clinical trials of REZPEG. Lilly denies the remaining allegations in Paragraph 23.

24. Paragraph 24 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it.

25. Paragraph 25 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it.

26. Lilly admits that it hoped REZPEG would show therapeutic potential. Lilly admits the areas of focus in the fall of 2017 were rheumatology (e.g., lupus), gastrointestinal disorders, and dermatology. Lilly admits it and Nektar agreed lupus would be the lead indication. Lilly admits that Paragraph 26 quotes from October 2017 Lilly-Nektar Joint Product Team ("JPT") meeting minutes. Lilly admits that over the next several years, Lilly and Nektar undertook clinical investigation of REZPEG as a moderate-to-severe systemic lupus erythematosus treatment in the systemic lupus erythematosus clinical trial discussed below. Lilly denies the remaining allegations in Paragraph 26.

27. Lilly admits that early in 2018 Lilly and Nektar discussed expanding REZPEG development to treat dermatological disorders. Lilly admits that Paragraph 27 accurately quotes excerpted language from March 2018 and May 2018 JPT meeting minutes. Lilly admits the parties decided to undertake Phase 1b atopic dermatitis and plaque psoriasis clinical trials. Lilly denies the remaining allegations in Paragraph 27.

Rise of Dupixent® and Lilly's Dermira Acquisition (2019-2020)

28. Lilly admits that, in the Fall of 2019, Lilly was preparing to undertake studies of REZPEG in atopic dermatitis and plaque psoriasis patients. Lilly also admits that it had been pursuing a small-molecule (non-biologic) medication, baricitinib, as a possible moderate-to-severe atopic dermatitis therapy. Lilly denies the remaining allegations in Paragraph 28.

29. Lilly admits that it recognized the market opportunity for drugs that treat moderate-to-severe atopic dermatitis. Lilly admits that Sanofi/Regeneron's Dupixent® was approved in 2017 for the treatment of moderate-to-severe atopic dermatitis. Lilly admits that Paragraph 29 accurately quotes excerpted language from the cited source. Lilly denies the remaining allegations in Paragraph 29.

30. Lilly admits that it purchased Dermira, Inc. for approximately $1.1 billion in early 2020. Lilly admits that, at that time, Dermira had been developing an antibody, lebrikizumab, to treat moderate-to-severe atopic dermatitis. Lilly admits that lebrikizumab's mechanism of action is a monoclonal antibody that targets IL-13 with high binding affinity and slow dissociation rate, to specifically prevent the formation of the IL-13Rα1/IL-4Rα heterodimer complex and subsequent signaling. Lilly admits that Dupixent®'s mechanism of action is a human monoclonal antibody of the immunoglobulin G4 subclass that inhibits IL-4 and IL-13 signaling by specifically binding to the IL-4 receptor alpha subunit, which is shared by the IL-4 and IL-13 receptor complexes. Lilly admits that Paragraph 30 accurately quotes excerpted language from the cited source. Lilly admits it is presently seeking approval of lebrikizumab as a moderate-to-severe atopic dermatitis treatment. Lilly denies the remaining allegations in Paragraph 30.

31. Paragraph 31 characterizes Nektar's claims or states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly admits that, as is common in many clinical trials and set forth in FDA regulations, it engaged a subcontractor with the approval and consent of Nektar to conduct certain work on clinical trials for REZPEG. Lilly denies the remaining allegations in Paragraph 31.

32. Paragraph 32 characterizes Nektar's claims or states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly admits that a clinical trial sometimes involves the investment of thousands of man-hours and millions of dollars, in which subjects are exposed

to drugs which may cause side effects, requiring tight regulatory supervisions by the FDA. Lilly also admits that clinical trial sponsors must follow relevant FDA regulations, and they may have other contractually or legally imposed standards. Lilly denies that it failed to comply with its regulatory obligations or any other contractually or legally imposed standards. Lilly denies Nektar's suggestion that any alleged conduct by Lilly or the CRO, including the CRO's calculation error, endangered patient health. Lilly denies the remaining allegations in Paragraph 32.

33. Paragraph 33 characterizes Nektar's claims or states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly denies the allegations in Paragraph 33.

Lilly's Flawed Eczema Study Analysis and False Publication

34. Lilly admits the allegations in Paragraph 34.

35. Lilly admits the allegations in Paragraph 35.

36. Lilly admits the allegations in Paragraph 36.

37. Lilly admits that the Phase 1b atopic dermatitis study protocol contemplated that clinicians would use the EASI to evaluate patients at each visit during the trial. Lilly denies the remaining allegations in Paragraph 37.

38. Lilly denies the allegations in Paragraph 38.

39. Lilly admits that the maximum EASI score is 72. Lilly denies the remaining allegations in Paragraph 39.

40. Lilly denies the allegations in Paragraph 40.

41. Paragraph 41 characterizes Nektar's claims or states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly denies the allegations in Paragraph 41.

42. Lilly denies the allegations in Paragraph 42.

43. Lilly admits that interim analysis results from the Phase 1b atopic dermatitis trial were presented to Lilly management and investors at an Investor Day presentation in December 2021. Lilly denies the remaining allegations in Paragraph 43.

44. Lilly admits that Paragraph 44 accurately quotes excerpts of an email that Lilly's Senior Director in the Office of Alliance Management sent to Nektar employees and of the email's attachment. Lilly denies the remaining allegations in Paragraph 44.

45. Lilly admits that Lilly and Nektar jointly presented interim analysis results from the Phase 1b atopic dermatitis trial at the European Academy of Dermatology and Venereology (EADV) Congress. Lilly also admits that the abstract by Schleicher et al. titled "Efficacy and Safety of a Selective Regulatory T-Cell Inducing IL-2 Conjugate (LY3471851) in the Treatment of Atopic Dermatitis: A Phase 1 Randomised Study" contained the CRO's calculation error and reported REZPEG's anti-atopic dermatitis efficacy at the high dose (24 mg/kg) after 12 weeks of treatment as approximately 66%. Lilly denies the remaining allegations in Paragraph 45.

46. Lilly admits that Nektar's revised calculations of the clinical trial data show 83% efficacy in treating atopic dermatitis after 12 weeks of therapy. Lilly admits that the 2022 publication about the Phase 1b atopic dermatitis trial containing the calculation error reported that approximately 29% of patients had 75% or greater improvement from their baseline condition (the "EASI75" score) after taking high-dose REZPEG for 12 weeks. Lilly admits that Nektar's revised calculations of the clinical trial data show that 41% of patients taking high-dose REZPEG had 75% or greater improvement from their baseline condition. Lilly denies the remaining allegations in Paragraph 46.

47. Paragraph 47 purports to quote from, characterize, and/or cite an external source, which speaks for itself, and therefore no response is required. To the extent a response is required, Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the allegations in Paragraph 47, and denies those allegations on that basis. Lilly denies the remaining allegations in Paragraph 47.

48. Lilly admits that a Phase 2b moderate-to-severe atopic dermatitis trial of lebrikizumab showed that 250 mg of lebrikizumab every 2 weeks (following 500-mg loading dose at baseline and week 2) resulted in an approximately 72% least-squares mean percentage change from baseline EASI after a 16-week treatment period. Lilly admits that a Phase 2b moderate-to-severe atopic dermatitis trial of Dupixent® showed that 300 mg of Dupixent® every 2 weeks resulted in an approximately 68% least-squares mean percentage change from baseline EASI after a 16-week treatment period. Lilly denies the remaining allegations in Paragraph 48.

49. Paragraph 49 characterizes Nektar's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the allegations in Paragraph 49 about Nektar's knowledge, and

denies those allegations on that basis. Lilly denies that it "declined to share the underlying raw clinical data with Nektar" in the ordinary course of the parties' collaboration. Lilly denies the remaining allegations in Paragraph 49.

Lilly's Unreasonable Phase 2 REZPEG Study Design for Eczema

50. Lilly denies the allegations in Paragraph 50.

51. Lilly denies the allegations in Paragraph 51.

52. Lilly admits expressing concerns about ISRs that occurred after administration of REZPEG. Lilly also admits that biologic drugs and other therapeutic antibodies and fusion proteins can be administered either intravenously or under the skin (subcutaneously), including some of Lilly's own drugs. Paragraph 52 also purports to quote from, characterize, and/or cite an external source, which speaks for itself, and therefore no response is required. To the extent a response is required, Lilly lacks knowledge or information sufficient to form a belief concerning the truth of the allegations regarding Dupixent® in Paragraph 52, and denies those allegations on that basis. Lilly denies the remaining allegations in Paragraph 52.

53. Lilly admits that some patients injected with lebrikizumab experienced ISRs, including ISRs that are mostly mild or moderate in severity. Lilly denies the remaining allegations in Paragraph 53.

54. Lilly admits that in early single ascending dose (SAD) and multiple ascending dose (MAD) studies of REZPEG, Nektar did not solicit ISRs and reported to Lilly that all unsolicited ISRs, were Grade 1 or 2 and resolved without medical intervention. Lilly denies the remaining allegations in Paragraph 54.

55. Lilly denies the allegations in Paragraph 55.

56. Lilly admits that Lilly and Nektar discussed the design of a Phase 2 trial for REZPEG in spring 2022. Lilly also admits that, on or about June 8, 2022, Lilly provided Nektar with a presentation setting forth the proposed design of the REZPEG Phase 2 trial, titled "IL-2 Conjugate [REZPEG]: Atopic Dermatitis Phase 2B Interim Strategy." Lilly denies the remaining allegations in Paragraph 56.

57. Lilly admits that five potential opportunities for interim analyses of the study data were considered in the Phase 2 moderate-to-severe atopic dermatitis study design proposed in the June 8, 2022 presentation referenced in Paragraph 56. Lilly also admits that Paragraph 57 accurately quotes the excerpted language from the lebrikizumab Phase 2b publication, titled "Efficacy and Safety of

Lebrikizumab, a High-Affinity Interleukin 13 Inhibitor, in Adults With Moderate to Severe Atopic Dermatitis." Lilly denies the remaining allegations in Paragraph 57.

58. Lilly admits that Nektar accurately describes the threshold for the first interim analysis of the Phase 2 moderate-to-severe atopic dermatitis study proposed in the June 8, 2022 presentation to Nektar referenced in Paragraph 56. Lilly denies that the practical effect of the Phase 2 moderate-to-severe atopic dermatitis study design was to give Lilly an excuse to stop that study quickly. Lilly denies the remaining allegations in Paragraph 58.

59. Lilly admits that Nektar accurately describes the futility criteria for the first interim analysis of the Phase 2 moderate-to-severe atopic dermatitis study contemplated as of June 8, 2022. Lilly denies that this proposal was unreasonable, extremely stringent, and/or intended to kill REZPEG development as early as possible. Lilly denies the remaining allegations in Paragraph 59.

60. Lilly admits that Nektar objected to Lilly's proposal for five potential interim analyses. Lilly denies the remaining allegations in Paragraph 60.

61. Lilly admits that, in an August 2022 meeting with Nektar, Lilly asserted that REZPEG "ISRs seen to date are above and beyond what are typically seen with biologics." Lilly denies the remaining allegations in Paragraph 61.

62. Lilly admits that Paragraph 62 accurately quotes the excerpted language from minutes of an August 5, 2022 JPT meeting. Lilly admits that it discussed with Nektar Lilly's quantitative market research in 2021 and qualitative market research in 2022, which showed that ISRs would have a negative impact on patient and provider preference in atopic dermatitis and systemic lupus erythematosus therapy. Lilly admits that Nektar told Lilly that it would be helpful to see the details of the market research results and claimed that a delay in the start to the Phase 2 study could impact the lead that REZPEG had relative to other IL-2 therapies. Lilly admits that Nektar also requested to see the top or most frequent reasons for discontinuation and the pooled discontinuation rates from the clinical studies and suggested that the Phase 1b atopic dermatitis study participants should be polled to understand ISR impact and build the parties' understanding of risks and benefits. Nektar also asked how Lilly was characterizing ISRs and suggested to be cautious when reporting low (1-2) grade reactions as severe, to which Lilly responded that ISRs seen

to date were above and beyond what are typically seen with biologics. Lilly denies the remaining allegations in Paragraph 62.

63. Lilly admits that it explained to Nektar that "there has been a holistic assessment of data seen to date which includes available ISR data" and that "high efficacy" of REZPEG "would be key in helping to offset ISR impact." Lilly denies the remaining allegations in Paragraph 63.

Lilly's Flawed Psoriasis Study Analysis

64. Lilly denies the allegations in Paragraph 64.

65. Lilly admits the allegations in Paragraph 65.

66. Lilly admits the allegations in Paragraph 66.

67. Lilly admits that REZPEG efficacy data in the Phase 1b plaque psoriasis study was collected using PASI. Lilly also admits that the CRO made a similar calculation error in the Phase 1b plaque psoriasis study to the one it made in the Phase 1b atopic dermatitis study, and that Nektar was informed of this in August 2023. Lilly denies the remaining allegations in Paragraph 67.

68. Lilly denies the allegations in Paragraph 68.

69. Lilly admits that an abstract by Forman et al. titled "Efficacy and Safety of a Selective Regulatory T-Cell Inducing IL-2 Conjugate (LY3471851) in the Treatment of Psoriasis: A Phase 1 Randomised Study" presenting data from the Phase 1b plaque psoriasis study was published at the EADV Congress on or about September 7-10, 2022. Lilly admits that the foregoing abstract showed that 11% of patients receiving REZPEG achieved 75% or greater improvement from their baseline condition (a "PASI75" score). Lilly admits that Nektar's revised calculations showed that 21% of patients receiving REZPEG achieved 75% or greater improvement from their baseline condition. Lilly denies the remaining allegations in Paragraph 69.

Lilly's Flawed Lupus Study Conduct and Analysis

70. Lilly admits that, beginning on or about August 19, 2020, and continuing through about February 16, 2023, Lilly oversaw a Phase 2 study of REZPEG in systemic lupus erythematosus patients, titled "A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of LY3471851 (NKTR-358) in Adults With Systemic Lupus Erythematosus" (study code: J1P-MC-KFAJ). Lilly admits that this lupus

study was designed to evaluate REZPEG's efficacy and safety versus placebo in systemic lupus erythematosus patients. Lilly denies the remaining allegations in Paragraph 70.

71. Lilly admits that it planned the Phase 2 systemic lupus erythematosus study with Nektar, including a sufficient patient pool to adequately power the study. Lilly also admits that some patients discontinued participating in the study. Lilly denies the remaining allegations in Paragraph 71.

72. Lilly denies the allegations in Paragraph 72.

73. Lilly denies the allegations in Paragraph 73.

74. Lilly denies the allegations in Paragraph 74.

75. Lilly denies the allegations in Paragraph 75.

Termination of Nektar-Lilly Partnership

76. Paragraph 76 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies the remaining allegations in Paragraph 76.

77. Lilly admits that, on April 23, 2023, after Nektar asked for rights to REZPEG to be returned to Nektar, Lilly notified Nektar that Lilly was terminating the Agreement pursuant to section 11.2. Lilly denies the remaining allegations in Paragraph 77.

78. Lilly admits that, the day after the termination, April 24, 2023, Nektar requested materials associated with Lilly's REZPEG clinical studies. Paragraph 78 also excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies the remaining allegations in Paragraph 78.

79. Lilly admits that it has been cooperating and continues to cooperate with Nektar to return materials owed to it under the Agreement, including raw data from REZPEG's clinical studies. Lilly denies the remaining allegations in Paragraph 79.

FIRST CAUSE OF ACTION

(Breach of Contract)

80. Lilly admits that it sent a letter to Nektar on June 21, 2023 stating that many of the documents in the Trial Master Files ("TMFs") for REZPEG "implicate confidentiality obligations Lilly has to third parties, privilege and privacy rights of third parties, and other legal obligations." Lilly also

admits that, in the same letter, it indicated that "Lilly must complete additional review and (potentially) redaction in order to comply with those obligations, regulations, and legal requirements," prior to transferring them to Nektar. Lilly denies the remaining allegations in Paragraph 80.

81. Lilly repeats and incorporates by reference each and every response set forth in this Answer as if fully set forth herein.

82. Lilly admits the allegations in Paragraph 82.

83. Lilly admits the allegations in Paragraph 83.

84. Paragraph 84 characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies the remaining allegations under Paragraph 84.

85. Paragraph 85 characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Paragraph 85 also characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly denies the remaining allegations in Paragraph 85.

86. Paragraph 86 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies that Plaintiff's claims have merit and denies that Plaintiff is entitled to any relief.

87. Paragraph 87 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies that Plaintiff's claims have merit and denies that Plaintiff is entitled to any relief.

88. Paragraph 88 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies that Plaintiff's claims have merit and denies that Plaintiff is entitled to any relief.

89. Lilly denies the allegations in Paragraph 89.

90. Lilly denies the allegations in Paragraph 90.

Lilly Breached the Agreement by Using the Botched Math in the Eczema and Psoriasis Studies

91. Lilly denies the allegations in Paragraph 91.

92. Paragraph 92 excerpts and characterizes the contents of the Agreement. The Agreement speaks for itself, and Lilly denies any allegations inconsistent with it. Lilly denies that Plaintiff's claims have merit and denies that Plaintiff is entitled to any relief.

93. Lilly denies the allegations in Paragraph 93.

94. Lilly denies the allegations in Paragraph 94.

Lilly's Eczema Phase 2 Study Design Breached the Agreement

95. Lilly denies the allegations in Paragraph 95.

96. Lilly admits that five potential opportunities for interim analyses of the study data for the Phase 2 eczema study were considered. Lilly denies the remaining allegations in Paragraph 96.

97. Lilly denies the allegations in Paragraph 97.

98. Lilly denies the allegations in Paragraph 98.

99. Lilly denies the allegations in Paragraph 99.

100. Lilly denies the allegations in Paragraph 100.

Lilly's Conduct of the Lupus Study Breached the Agreement

101. Lilly denies the allegations in Paragraph 101.

102. Lilly denies the allegations in Paragraph 102.

103. Lilly denies the allegations in Paragraph 103.

104. Lilly denies the allegations in Paragraph 104.

SECOND CAUSE OF ACTION

(Breach of the Implied Covenant of Good Faith and Fair Dealing)

105. Lilly repeats and incorporates by reference each and every response set forth in this Answer as if fully set forth herein.

106. Lilly admits that Lilly and Nektar entered into the Agreement on or about July 23, 2017. Lilly also admits that, under the Agreement, the parties had certain rights and obligations. Lilly denies the remaining allegations in Paragraph 106.

107. Lilly admits the allegations in Paragraph 107.

108. Lilly denies the allegations in Paragraph 108.

109. Lilly denies the allegations in Paragraph 109.

110. Paragraph 110 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly denies that Plaintiff's claims have merit, denies that Plaintiff is entitled to any relief, and denies the allegations in this Paragraph.

111. Paragraph 111 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Lilly denies that Plaintiff's claims have merit, denies that Plaintiff is entitled to any relief, and denies the allegations in this Paragraph.

112. Lilly denies the allegations in Paragraph 112.

113. Lilly denies the allegations in Paragraph 113.

THIRD CAUSE OF ACTION

(Negligent Misrepresentation)

114. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

115. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

116. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

117. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

118. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

119. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

120. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

121. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

FOURTH CAUSE OF ACTION

(Unfair Competition Under Cal. Bus. & Prof. Code Section 172000)

122. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

123. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

124. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

125. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

126. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

127. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

128. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

129. No response necessary. Claim dismissed per Minute Order (ECF No. 45).

PRAYER FOR RELIEF

The Prayer for Relief characterizes Nektar's demand for judgment, and therefore does not require a response. To the extent a response is required, Lilly denies the allegations in the Prayer for Relief, and denies that any of the requested relief should be granted. Further, Nektar's request for punitive damages was dismissed per Minute Order (ECF No. 45) and, therefore, no response to that request is required. To the extent a response is required as to Nektar's request for punitive damages, Lilly denies that punitive damages should be awarded.

JURY DEMAND

Lilly admits that Nektar purports to demand a trial by jury. To the extent Nektar purports to state a conclusion of law, no response is required.

GENERAL DENIAL AND DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Lilly in this matter. Lilly, therefore, asserts said defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Lilly may withdraw any of these defenses as may be appropriate. Lilly has not knowingly or intentionally waived any applicable defenses, counterclaims, or other claims or defenses, and reserves the right to assert and rely on such other applicable defenses and claims as may become available or apparent during discovery in these proceedings. Further answering and by way of additional defense, Lilly states the following:

FIRST AFFIRMATIVE DEFENSE

The claims in the Complaint are barred, in whole or in part, by the doctrine of waiver and/or estoppel.

SECOND AFFIRMATIVE DEFENSE

Lilly affirmatively pleads and relies upon all defenses and affirmative defenses set forth in Rule 8(c) and 12(b) of the Federal Rules of Civil Procedure that are or may hereafter become applicable to the claims made herein, and expressly reserves any and all other defenses, including affirmative defenses which maybe become apparent during the course of discovery.

DATED: March 29, 2024

Respectfully submitted,

s/ Ryan Moorman

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